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No. ____

In The

Supreme Court of the United States

October Term, 1995

SAM FELDT,

Cross-Petitioner,

v.

MENTOR CORPORATION,

Cross-Respondent.

On Cross-Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

CONDITIONAL CROSS-PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Do the Medical Device Amendments to the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360c *et seq.*, preempt state-law claims to recover for injuries caused by a defective medical device?

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Sam Feldt petitions for review of a ruling of the United States Court of Appeals for the Fifth Circuit concerning injuries that were caused by Mentor Corporation's allegedly defective inflatable penile prosthesis. Specifically, the court of appeals held that cross-petitioner's state-law claims based on failure to warn were preempted; implied warranty claims based on failure to warn were preempted; and state deceptive trade practices claims based on failure to warn were preempted. Cross-petitioner seeks review of the ruling below on the claims that the court held were preempted.

The Fifth Circuit also held that cross-petitioner's claims based on the defective design of the medical device were not preempted. These claims were based on negligence, strict liability, implied warranty, and state deceptive trade practices. The holding below that these claims based on the design of the product are not preempted forms the basis of Mentor's petition for writ of certiorari filed on December 26, 1995. *Mentor Corp. v. Feldt*, No. 95-1037.

OPINIONS BELOW

The opinion of the court of appeals is reported at 61 F.3d 431 (5th Cir. 1995), and is reproduced in the appendix to the petition of Mentor (Pet. App.) at Appendix A (Pet. App. 1-17). The unreported opinion of the United States District Court for the Southern District of Texas is reproduced in the appendix to the petition at Appendix C (Pet. App. 20-29).

JURISDICTION

The judgment of the court of appeals was entered on August 21, 1995. Mentor Corporation filed a timely petition for rehearing, which was denied on September 26, 1995, and is reproduced in the appendix to the petition at Appendix B (Pet. App. 18-19). The petition for writ of certiorari in No. 95-1037 was filed on December 26, 1995, and placed on the docket on December 27, 1995. This cross-petition is being filed within 30 days thereafter. This Court has jurisdiction over the petition and this cross-petition under 28 U.S.C. § 1254(1) and Rule 12.5 of this Court.

STATUTES AND REGULATIONS INVOLVED

This case involves the preemption provision of the Medical Device Amendments of 1976 (MDA) to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360k. Also involved is the regulation of the Food and Drug Administration (FDA) interpreting the preemption statute, 21 C.F.R. § 808.1(d).

21 U.S.C. § 360k(a) provides in pertinent part:

[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 C.F.R. § 808.1(d) provides in pertinent part:

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

STATEMENT OF THE CASE

The question presented is essentially that presented in *Lohr v. Medtronic, Inc.*, 56 F.3d 1335 (11th Cir. 1995),

cert. granted, 1996 U.S. LEXIS 698 (U.S. Jan. 19, 1996) (Nos. 95-754, 95-886). The question presented is also essentially the same as that presented in two other cases pending before this Court on petitions for writs of certiorari: *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 194 (4th Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3439 (U.S. Dec. 22, 1995) (No. 95-1010); and *English v. Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995), *petition for cert. filed*, 64 U.S.L.W. 3469 (U.S. Dec. 26, 1995) (No. 95-1034). In light of this Court granting review in *Lohr*, as well as the already extensive briefing on the question presented, this cross-petition will be kept brief.

A. Factual and Procedural Background.

In late 1988 Sam Feldt was implanted with a Mentor GFS inflatable penile prosthesis, a medical device designed to treat erectile impotence. The device was designed, manufactured, and sold by Mentor Corporation. In 1991 the device failed and suit was filed in state court in Texas seeking recovery under various state law causes of action including negligence, implied and express warranty, the Texas Deceptive Trade Practices Act, and products liability based on defects in design, marketing, and manufacturing. The manufacturing claims were later voluntarily dropped by Mr. Feldt before the district court ruled on the summary judgment motion. The defendant timely removed the case to federal court based on diversity of citizenship. 28 U.S.C. §§ 1332, 1441.

The MDA became effective on May 28, 1976. Before that date medical devices were essentially unregulated. The regulatory scheme set forth in the MDA provides for

the classification of medical devices into three classes. 21 U.S.C. § 360c. The least dangerous devices were to be classified as Class I devices and regulated by general controls. 21 U.S.C. § 360c(a)(1)(A). Class II devices were to have additional special controls, including performance standards. 21 U.S.C. § 360c(a)(1)(B). Class III devices encompass the most potentially dangerous devices, and to ensure safety and effectiveness, and to protect the American public, Class III devices were to be subject to premarket approval (PMA). 21 U.S.C. § 360c(a)(1)(C).

Most Class III devices, however, do not reach the market after undergoing the PMA process. Instead, there are exceptions to the general PMA rule. First, devices that are of the same model as a device that was already on the market prior to the effective date of the MDA, May 28, 1976, are initially not subject to premarket approval. These are so-called "grandfathered" devices. Second, devices that are "substantially equivalent" to devices marketed prior to May 28, 1976, can be marketed by filing with the FDA what is known as a 510(k) notification submission. 21 U.S.C. § 360(k).

All Class III devices will eventually have to undergo the PMA process and obtain approval. But even now, almost twenty years since the MDA took effect, many Class III devices remain on the market without having undergone the PMA process. The device involved in this case, the inflatable penile prosthesis, is a Class III device. 21 C.F.R. § 876.3350. It is undisputed that the device is a 510(k) device and has not undergone the PMA process. Pet. App. at 5. Contrary to Mentor's assertion that the "prosthesis was an FDA-approved Class III medical

device" (Petition in No. 95-1037 at 3), the FDA has specifically taken the position that a 510(k) determination of substantial equivalence "does not in any way denote official approval of the device." 21 C.F.R. § 807.97.

B. The District Court Proceedings.

Mentor Corporation raised eighteen affirmative defenses, including the complete preemption of all state-law claims. On July 11, 1994, the district court granted summary judgment in favor of Mentor on all claims. The court held that the claims were preempted based upon two grounds. First, the court held that the 510(k) notification process imposed requirements that preempted all of Mr. Feldt's claims. Pet. App. at 27. Second, the court held that the labelling and good manufacturing practices (GMP) regulations, which are general controls, imposed requirements that preempted Mr. Feldt's claims. Pet. App. at 28.

The cross-petitioner urged the district court to defer to the FDA's preemption interpretation that requires "specific requirements applicable to a particular device under the act." 21 C.F.R. § 808.1(d). The general rule is that "a court may not substitute its own construction of a statutory provision for a reasonable interpretation" by the agency that administers the statute. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984). Although there are no device specific regulations for the Mentor GFS, the district court held that there was total preemption. Pet. App. at 28-29.

In further support of his position that his claims were not preempted, cross-petitioner cited the case of *Larsen v.*

Pacesetters Systems, Inc., 837 P.2d 1273 (Haw. 1992). The Hawaii Supreme Court had held that the 510(k) process does not establish preemptive requirements. *Larsen*, 837 P.2d at 1282. The district court determined that the *Larsen* decision, a decision from a state court of last resort, was contrary to Fifth Circuit precedent. Pet. App. at 27 (citing *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993)).

C. The Court of Appeals' Opinion.

The Fifth Circuit disagreed with the district court that the 510(k) notification process constitutes a requirement that would preempt all of Mr. Feldt's claims. Pet. App. at 13. The court also refused to broadly hold that because there are some GMP's that would apply to the device, all of Mr. Feldt's claims would be preempted. Pet. App. at 12. Nevertheless, the court below, following Fifth Circuit precedent, held that claims based upon inadequate warnings or labeling would be preempted by the general controls, including GMP's. Pet. App. at 11.

The court below decided this case against the backdrop of three Fifth Circuit opinions that had previously addressed the issue of medical device preemption. Pet. App. at 9-11. In the Class II context the court had previously held that claims involving design defects were not preempted, but that warning claims were preempted when there were specific labeling requirements for the device. Pet. App. at 8 (citing *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989)). In regard to a Class III product that had gone through the PMA process, the court had previously held that design, manufacturing,

and warning claims were all preempted. Pet. App. at 8-9 (citing *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993)). In the third case the court had held that even general controls such as GMP's have preemptive effect. Pet. App. at 9-11 (citing *Reeves v. AcroMed Corp.*, 44 F.3d 300 (5th Cir.), *cert. denied*, 115 S. Ct. 2251 (1995)). The Fifth Circuit is in conflict with other circuits and decided the claims other than the design-related claims incorrectly.

REASONS FOR GRANTING THE WRIT

THE DECISION BELOW CONFLICTS WITH DECISIONS OF OTHER COURTS OF APPEALS ON AN IMPORTANT ISSUE OF FEDERAL LAW.

The extent to which a consumer can proceed with a claim for damages for injuries resulting from a defective medical device now depends upon the circuit. In the Ninth Circuit, none of Mr. Feldt's claims would be preempted. In a case involving Zyderm, the same Class III, PMA-approved product at issue in the Fifth Circuit *Stamps* case, the Ninth Circuit held that state common law is a law of general applicability and that the MDA does not preempt laws of general applicability. *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995), *amended*, 1995 U.S. App. LEXIS 32816, *17, *reh'g and reh'g en banc denied*, (January 16, 1996). Although the *Kennedy* case is relegated to a passing reference in a footnote in Mentor's petition in No. 95-1037 at 9 n.4, its importance cannot be ignored. In the Ninth Circuit an individual retains all of his or her common law rights to sue for damages for an injury received from a medical device.

The Fifth Circuit mistakenly held that cross-petitioner's claims other than the design-related claims were preempted. In the first instance, the court below mistakenly held that the preemption statute encompasses state common law claims. The court failed to properly consider the language, structure, and purpose of the MDA. The Fifth Circuit's decision below is at odds with the Ninth Circuit's decision in *Kennedy* that the MDA does not preempt common law actions at all.

Second, the lower court refused to defer to the FDA interpretation that requires specific requirements relating to a particular device before preemption would apply. General controls, including general labelling regulations, are not device specific. The lower court incorrectly held that general FDA requirements trigger preemption of claims. The warnings at issue in *Moore* were device specific for tampons. *Moore*, 867 F.2d at 246. In contrast, the labelling and warnings at issue here were not device specific for penile prostheses.

In the Third Circuit the Mentor GFS inflatable penile prosthesis was also the product at issue in the *English* case. Although the product and manufacturer were the same, the analysis and result were different from that reached by the Fifth Circuit. The Third Circuit, in conflict with the Fifth Circuit, held that the 510(k) process was a requirement that preempted state law claims. *English*, 67 F.3d at 482. As a result, design-related claims are now preempted in the Third Circuit, even though the design in question is based upon the design of a product that was on the market prior to the adoption of the MDA in 1976. This is the subject of Mentor's petition for review, but the broader question of differing circuit results and analyses

carries over to the other claims and therefore warrants review of the decision below in its entirety.

The circuit court decisions now run the spectrum from no preemption, to some preemption, to total preemption. A circuit by circuit survey of the conflicting preemption decisions is set forth in the petitioners' brief in *Duvall*. (No. 95-1010 at 11-13). Following the mandate of "accuracy, brevity, and clarity" under Supreme Court Rule 14(4), those cases will not be discussed again here. Since the petitions for writs of certiorari were filed in *Duvall* (95-1010), *English* (95-1034), and *Feldt* (95-1037), the Ninth Circuit has denied the suggestion for rehearing *en banc* in *Kennedy*, and this Court has granted the petitions for writs of certiorari in *Lohr* (Nos. 95-754, 95-886). There is now a mature circuit conflict in an area of great importance that warrants Supreme Court review.

CONCLUSION

By granting the petition for a writ of certiorari in the *Lohr* case, this Court has already determined that the issue of the scope of MDA preemption is ripe for review. Mr. Feldt has filed his conditional cross-petition so that in the event the Court determines that an additional case is necessary to fully explore the issue, the Court will have the entire preemption controversy to decide, and not just the narrow issue of the preemption of design claims.

In the event that the Court grants Mentor Corporation's petition for a writ of certiorari, this conditional

cross-petition for a writ of certiorari should also be granted.

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October Term, 1995

SAM FELDT,

Cross-Petitioner,

v.

MENTOR CORPORATION,

Cross-Respondent.

On Cross-Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

BRIEF FOR CROSS-RESPONDENT IN RESPECT OF THE CONDITIONAL CROSS-PETITION

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QUESTION RESTATED

Do the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360c *et seq.*, preempt state law claims that allege that the plaintiff was injured by a medical device that lacked an adequate warning?

BRIEF FOR CROSS-RESPONDENT IN RESPECT OF THE CONDITIONAL CROSS-PETITION

On January 19, 1996, this Court granted certiorari in *Lohr v. Medtronic, Inc.*, 56 F.3d 1335 (C.A.11 1995), *cert. granted*, Nos. 95-754 and 95-886. *Lohr* presents, among other issues, whether state law claims for negligence and strict liability are preempted by federal law when the plaintiff alleges injury caused by a manufacturer's failure to warn about a medical device.

Similarly, the conditional cross-petition in this case asks the Court to decide whether the Medical Device Amendments to the Food, Drug and Cosmetic Act (21 U.S.C. § 360c, *et seq.*) preempt claims asserting liability under state law for a failure to warn about a medical device that allegedly caused injury.[1] In this case, the Fifth Circuit found preempted state law claims based on negligence, strict liability, implied warranty, and the Texas deceptive trade practices act. Each such preempted claim rested on the assertion of a failure to warn about the medical device at issue.

Thus, there appears to be either similarity or overlap between some of the issues before the Court in *Lohr* and some of the issues presented by the conditional cross-petition.

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[1] The question presented by the cross-petition is inartfully broad, referring to preemption of "state-law claims" without precision or differentiation. However, as the petition makes clear (at p. 1) the specific preempted claims at issue in this case are each premised on the theory of a failure to warn about the medical device at issue.

DATED: February 26, 1996.

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